

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Bowen-Leaver, et al.

Serial No.: 09/897,871

Group Art Unit: 1617

Filed: July 2, 2001

Examiner: Yu, Gina C.

For: Ringing Nanogel Compositions

**Remarks**

In the final office action of June 3, 2004, rejections of the claims of the present invention under 35 U.S.C. §103 as being unpatentable over three sets of references are maintained. Applicants previously asserted that the cited references fail to teach or suggest a self-structured nanogel like that of the present invention. Pursuant to 35 U.S.C. §103, a *prima facie* case of obviousness requires, *inter alia*, establishing that prior art reference(s) teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The ringing nanogels of the present invention, as amended, contain an oil phase and a silicone oil component comprising at least one volatile oil that are self-structured by a high shear/pressure treatment and have a difference in complex viscosity of at least about 10,000 poise under oscillation stress in the range of about 0 to 5,000 (dyne/cm<sup>2</sup>). The nanogels of the present invention upon application to the skin feel pleasantly smooth at first and then transitions to a wet-like feel that is refreshing on the skin. However, because the composition is a gel, the consistency is not thin and drippy like water, and it is not tacky like other gels. This feeling and consistency is surprising especially since it is achieved with the oil phase and the silicone component that are self-structured. This is not taught or suggested by the cited references.

**The '551 Reference**

In response to Applicants' previous assertions, the Examiner noted in the Advisory Action of December 27, 2004 that the '551 reference is directed to a transparent emulsion gel with oil particles that are less than 100 nm, and that the '551 thickeners are not absolutely present in the '551 transparent gels. The Examiner also asserts that the '551 reference teaches that its alleged invention is to use emulsifiers or polymers to form a hydrophobic network and therefore a gel without thi [sic]. However, Applicants respectfully disagree that this is what the '551 reference teaches. The '551 teachings must be made by reading the reference in its entirety and not in isolated segments that favor one opinion or another. "It is not permissible to pick and choose only so much of any given reference as will support a given position and

ignore the reference in its totality.” *Lubrizol Corp. V. Exxon Corp.*, 986 F. supp. 302, 322, 7 USPQ2d 1513, 1527 (N.D. Ohio 1988). At no point in the ‘551 reference is the preparation of the microemulsion gel taught without the presence of either a thickener or a crosslinker.

As taught in the ‘551 reference, at column 8, line 41 to 12, the ‘551 compositions include microemulsions without a crosslinker component used as precursors for the gels of high viscosity obtained with the crosslinker; but that can also be the ‘551 gels. Thus, the ‘551 reference distinguishes between the types of gels that can be formed with and without the crosslinker. But this is not to say that the ‘551 reference teaches that when its gels are made without a crosslinker that they are made without a thickener. Specifically, at column 21, lines 39 to 42, of the ‘551 reference it is noted that microemulsion gels are prepared with the addition of one or more thickeners. Afterwards, it is noted in the ‘551 reference, at column 21, lines 43 to 45, that it is particularly advantageous to first prepare low viscosity microemulsions and then add a crosslinker to make a gel. Next, microemulsions prepared with lecithin can be also made into a gel by the addition of one or more thickeners. Finally, every example in the ‘551 reference uses a crosslinker. Applicants assert that in light of the ‘551 reference in its entirety, there is no teaching or suggestion in the ‘551 reference that ‘551 gels can be made without either the presence of a thickener or a crosslinker. Thus, Applicants maintain their assertion that no gels are taught in the ‘551 reference without the presence of either a thickener or a crosslinker.

In the Advisory Action, the Examiner finds that Applicants’ argument that the present invention is devoid of thickeners or gelling agents is not commensurate with the scope of the present claims because “what specific compounds are considered thickeners and gelling agents which Applicants have excluded.” Applicants interpret this to mean that specific thickeners and gelling agents have not been delineated as being excluded. As an alternative, Applicants have positively recited and distinguished the present invention, as amended, over the prior art by directing the claims to a “self-structured” oil phase and volatile silicone component by a high shear/pressure treatment. Specifically, this is further elaborated on and connected with the absence of thickeners and emulsifiers at page 4, paragraph 14, wherein it explains that the ringing nanogels of the present invention are made without using thickening agents such as those that are known and described in the CTFA. Further at page 7, paragraph 21, the compositions of the present invention are thickened when the silicone component, water phase and oil phase self-structure during the high shear/pressure treatment.

In response to Applicants’ previous arguments to the first obviousness rejection based on U.S. Patent No. 6,468,551, “the ‘551 reference,” the Examiner asserts that Claim 1 of the present invention does not require that the composition be a “ringing” gel. However, this does not respond to Applicants’ previous argument that the ‘551 reference fails to teach or suggest the low amount of emulsifiers in the present invention without the need for not only emulsifiers, but also thickeners and/or crosslinking agents. The ‘551

teaches that the amount of emulsifier can be reduced because thickeners can be added. As long as the thickener is present in combination with the lower amount of emulsifier, the '551 gel is clearly not self-structured and one of ordinary skill in the art would understand that the '551 gel is unlike that of the present invention. The '551 reference suggests that the amount of the emulsifier can be reduced not in an absolute sense but on a contingent basis. As repeatedly mentioned in Applicants Response of February 5, 2004, and Response of June 3, 2004, at column 25, line 56 to column 26, line 7, of the '551 reference it is taught that the amount of emulsifier is obtained because it is possible for thickeners to be used.

Advantageous O/W microemulsions and microemulsion gels can be obtained, the proportion of the O/W emulsifier for example being less than . . . 15% by weight, based on the total weight of the microemulsion . . . , **it being possible for the thickener or thickeners used according to the invention to be added at any point in time of the preparation.**

One of ordinary skill in the art would understand this language to mean that the amounts of emulsifier suggested by the '551 reference can be used because the gel is made with the thickener. Therefore, the '551 gel is structured by a combination of emulsifier and thickener – it is not self-structured. This is unlike the present invention, as amended, where the gel is self-structured by the high shear/pressure treatment without physically adding another material, like that of a thickener or a crosslinking agent, to the gel. This has not been taught or suggested by the '551 reference. Therefore, the '551 reference fails to render the present invention obvious, and a *prima facie* case of obviousness has not been made.

The Examiner notes that there is evidence to show that the prior art nanoemulsion gel made from the same oil/silicone oils are not “self-structured” while the present invention is. Further, the Examiner asserts that the '551 reference teaches that thickeners are used only “if possible.” Applicants respectfully traverse this assertion because upon review of the '551 reference in its entirety the “possibility” referred to by the Examiner is essentially the contingency referred to by the '551 reference. The '551 reference would be understood by one of ordinary skill in the art to reasonably teach or suggest that the emulsifier amount can be reduced contingent upon the ability to use thickener or a crosslinking agent as a substitute. Thus, there is nothing “the same” about the self-structured gels of the present invention and the low volatile oil containing gels that are crosslinked or that contain thickeners in combination with the lower level of emulsifiers in the '551 reference. The '551 gels are not taught as being structured in the absence of thickeners or crosslinking agents.

As previously presented in their Response of February 5, 2004, the term “self-structuring” as it is used in the present specification excludes gels that are made according to the teachings of the '551 reference. As described in the present specification at page 3, paragraph [0008], the self-structuring of the oil phase and the silicone component thickens the composition and makes the nanogel. More detail about

thickening by self-structuring, and not by adding another physical material, is described in the present specification at page 7, paragraph [00021], where it is noted that the composition is thickened when the silicone component, the water phase, and the oil phase self-structure during the high shear/pressure treatment. Even the '551 reference recognizes, at column 24, lines 38 to 42, the high pressure homogenization process for creating nanoemulsions; but that the principle of crosslinking leads to the gel. The '551 reference teaches that there is a difference between making a nanoemulsion and a nanogel, and that high-pressure homogenization by itself does not make the gel. Thus, while the '551 reference teaches that low viscosity microemulsions or gels can be formed simply by adding water to a mixture of components in an oil phase, it does not teach that the high-pressure homogenization process will result in a gel, either a high viscosity microemulsion gel or a nanoemulsion gel. The '551 reference teaches that high viscosity microemulsion gels or nanoemulsion gels are formed by the presence of a crosslinker or a thickener.

One of ordinary skill in the art would understand the difference between a self-structured gel of the present invention and a gel structured by a thickener or crosslinker as taught in the '551 reference. In the '551 reference, because the gel is structured by the addition of another physical material, namely, the thickener or the crosslinker, the gel is not self-structured as in the present invention. In the present invention, by discovering what has not been known before, namely, that the silicone oil and the silicone component can be self-structured to have a unique rheological profile described in the present claims. In other words, the reduced emulsifier in the present invention is achieved not with the addition of another physical structuring agent as it is in the '551 reference. Further, as shown in Figure 1 and discussed at page 15, paragraph 15, the rheological profile of the gels of the present invention is not achieved when a gel is made with a thickener. There is no teaching or suggestion in the '551 reference that a gel can be formed based on the properties of the oil phase without the presence of thickeners or crosslinking agents.

The '551 reference fails to teach or suggest that a gel can be formed as a result of the properties of its oil phase. Further, no recognition is found in the '551 reference of the ability of a volatile silicone oil in combination with an oil phase to contribute to the structuring of a gel because structure of the gel is achieved with either thickeners or crosslinking agents. However, with the present invention, the self-structuring of the oil phase and the volatile silicone oil component thickens the composition and makes a nanogel. Unlike the cited prior art, no additional thickener, crosslinking agent or coupler is used in the present invention. As presented in the present specification at page 3, paragraph [0008], the nanogel of the present invention is made by subjecting a water phase, an oil phase, and a silicone component to a series of high shear/pressure treatments. As a result of these treatments, the oil phase and the silicone component self-structure to make the nanogel. This is also discussed at page 6, paragraph [00017] and page 7, paragraph [00021] of the present specification. The thickening of the nanogels of the present invention occurs in the absence of traditional viscosity increasing agents (i.e., thickeners or crosslinkers) as explained

at page 4, paragraphs [00012] and [00014] of the present specification. Further, as noted in the present specification, at page 5, paragraph [00015], the initial complex viscosity of the nanogel of the present invention is at least about 15,000 poise. The self-structuring of the oil phase and the silicone oil component is not taught or suggested by the '551 reference alone or in combination with any of the cited references all of which use thickeners, crosslinking agents or couplers. Therefore, Applicants request that the rejection of the claims of the present invention, as amended, based on the '551 reference be withdrawn.

#### The '551 and '818 References

Second, the Examiner rejects Claim 6 as being obvious in view of a combination of the '551 reference and U.S. Patent No. 4,026,818 issued to Claudelli (hereinafter referred to as the '818 reference.) The Examiner points out in response to Applicants previous arguments that the present claims are rejected in view of the collective teachings of the cited references. Applicants understand this and note that a collection is the sum of its individual parts. And, in applying this logic, Applicants were merely analyzing each reference before addressing, and in order to address the collective. This also applies to the third set of cited references discussed below. Therefore, as the collective aspect of Applicants' argument seems to have been missed, it is presented again. Not only does the '818 reference use a thickener, it uses a coupler, and therefore, the '818 compositions in combination with the '551 compositions is not a teaching or suggest of self-structuring nanogels of the present invention, as amended. Basically, as a collection, these two cited references fail to teach or suggest a self-structuring nanogel. They, collectively teach a composition containing lecithin, which is an emulsifier, and a coupler, as well as a thickener to achieve a gel with the low level of emulsifiers.

Further, the Examiner notes that lowering the concentration of emulsifier is suggested by the '818 reference. However, the '818 reference more specifically suggests at column 1, lines 49 to 50, to "lower ratios of emulsifier to oil." The ratio of surfactant to mineral oil in the '818 reference is noted at column 3, lines 2 to 5, and lines 17 to 20 as 1:1. Furthermore, the '818 reference mentions at column 1, lines 40 to 42, a high ratio of emulsifier to oil is noted as being 3:1. This actually teaches away from the present invention since it is the inverse of a high ratio of emulsifier to oil, namely, a high ratio of oil to emulsifier of about 5:1 as explained at page 8, paragraph [00022]. Oil is at least five times as great as the emulsifier in the present invention. Therefore, the '818 reference fails to teach or suggest the present invention, as amended, alone or in combination with the '551 reference because it fails to teach or suggest the ability of the oil phase to self structure (i.e., structure without a thickener or a coupler).

The '818 reference teaches transparent ringed gel compositions that use mineral oil, water, isostearic acid and (2 ethyl 1,3-dihydroxy) 2-propyl oleamide. There is no motivation to combine this reference with the '551 reference as the '818 gel system is completely different from that of the gel system

taught in the '551 reference. However, if there is any combination of the teachings that can be made between these two references it would be that different thickeners can be used with mineral oil to make a gel, namely, isostearic acid and (2 ethyl 1,3-dihydroxy) 2-propyl oleamide can be used as the thickener or crosslinker in the '551 reference. However, such a combination of these references fails to teach or suggest the present invention, as amended, because there remains no teaching or suggestion that an oil phase and a volatile silicone oil component can self-structure to form a gel without thickeners, couplers, or crosslinkers. Therefore, Applicants request that the Examiner's rejection based on this combination of references be withdrawn.

#### The '377, '818, and '551 References

Another reference, Kakoki et al. (U.S. Pat. No. 5,162,377; hereinafter "the '377 reference") is cited by the Examiner in combination with the '818 and the '551 references for rendering Claims 7 to 11, 13, 15, and 16 obvious (the third set of cited references). Previously, Applicants argued that there is a two step shearing process described in Claim 7 and a three step shearing process in Claim 8 of the present invention. Therefore, the two and three steps that are minimally used with the compositions of the present invention are not taught by the '377 reference, and therefore, this reference alone and in combination with the other cited references fails to teach or suggest the present invention. In response, the Examiner finds that Claim 8 which specifically is directed to shearing three times, falls within the prior art emulsion because it is necessarily subjected to treatment three times during the process of making the emulsion. However, Applicants point out that the ringing nanogel is not made in the prior art until 5 to 10 times. This means, according to the prior art, that after treatment three times one of ordinary skill in the art would not expect to make a ringing nanogel until an additional 3 to 7 times of treatment are applied. The surprising benefit of the present invention is that the nanogel can be made after only 2 or 3 times being subjected to the high shear/pressure treatment. This is certainly not taught or suggested by the combination of references to run the shear process 5 to 10 times. It takes less time and uses fewer resources to make the gel of the present invention that is sheared only three times. Further, the Examiner has with respect to the first set of cited references asserted that the claims of the present invention do not require a ringing nanogel. Applicants assert that as Claims 7 to 16 are all directed to specific methods for making ringing nanogels which involves a step of treating a composition containing a volatile silicone oil not taught by the cited references alone or in combination, minimally these contain allowable subject matter. There is no teaching in the '377 reference of treating a composition containing a volatile silicone oil. Therefore, one of ordinary skill in the art would not be based on the '377 make the present invention, in combination with the other cited references.

One of ordinary skill in the art would not combine the method taught in the '377 reference with the teachings of the '551 reference because the methods of the '377 reference are conducted on compositions

containing oils that are non-volatile in nature. The oils taught in the '377 reference are non-volatile and the '377 reference fails to teach or suggest that its methods can be applied to compositions containing volatile oils. Therefore, not only would one of ordinary skill in the art not make the combination suggested by the Examiner; but, the combination of the teachings in the '551 reference and the '377 reference fails to make the present invention. The '551 reference is the only reference that teaches a gel with a volatile silicone oil is the '551 reference. However, as discussed in the section above addressing this reference, the '551 reference fails to teach or suggest the making of a gel in the absence of a thickener or crosslinking agent. The '818 reference teaches a ringed gel made with a non-volatile oil, namely, mineral oil; but, the combination of '818 reference with the other cited references, would not make the present invention because the '377 reference fails to teach or suggest that its methods can be applied to compositions containing volatile silicone oil. Further, the '818 reference in combination with the '377 reference would not make the present invention because it would fail to include a volatile silicone oil. The present invention, as amended, relates to ringed nanogel compositions that comprise an oil phase and a volatile silicone oil component that self-structures when treated to a high shear/pressure treatment. The self-structuring oils thicken the composition and make a nanogel.

Because none the cited references alone nor in combination would lead one of ordinary skill in the art to the self-structuring compositions of the present invention, as amended, a *prima facie* case of obviousness has not been established. For the reasons stated above, Applicants request that the Examiner's rejection be withdrawn as Claims 1 to 3, 5 to 11, 13, 15, and 16 of the present application, as amended, satisfy the requirements of 35 U.S.C. §103(a).

### CONCLUSION

In view of the arguments presented above in the present submission, the claims are believed to be in condition for allowance, and issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

Date: March 3, 2005



Dorene M. Price (Reg. No. 43,018)  
Estee Lauder Companies  
155 Pinelawn Road  
Greenway Plaza, Suite 345 South  
Melville, NY 11747  
(631) 414-6087